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Sede Legale e Amministrazione  
20144 Milano (Italy) Via A. Solari 19 sc. 6

## QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgG RECOMBINANT

Code 91029

LOT.NO 042-C



2024-02



2022-11

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93029	E8640	MICROPLATE	040	2024-04	1
PF93529	D8640	CONJUGATE	040-1	2024-02	1
PF93910	1036	NEGATIVE CONTROL	174-2	2024-02	1
PF93829	B8640	POSITIVE CONTROL	039-1	2024-05	1
PF91829	C8640	CUT OFF CONTROL	039-1	2024-05	1
PF93619	1034	SUBSTRATE-HS	371	2024-06	1
PF30029	1031	DILUENT 3	051-1	2024-05	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1

### CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.061	<0,6 Cut Off
CUT OFF CONTROL	0.427	≥ 0.200
POSITIVE CONTROL	0.896	>1,5 Cut Off
CV%	8%	≤ 15%

*Evaluatin of the method according to the package inset in the attached document  
This batch has been manufactured and checked according to quality requirements.  
Hereby, it is released to distribution.*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE:

17.05.2023

### WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.



### CERTIFICATE OF ANALYSIS

KIT: **HERPES SIMPLEX 2 IgG RECOMBINANT**  
 LOT: **042**  
 DATE OF TEST: **22/11/2022**

Code 91029  
 Code 91183

METHOD: ACCORDING TO THE PACKAGE INSERT


1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
	OD450 nm	<b>1.550</b>	
	CV%	<b>4%</b>	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	<b>1.568</b>	
	CV%	<b>6%</b>	<15%
2. BULK CONTROL date: 10/11/2022			
A) Average OD of Cut Off Control	OD 450 nm	<b>0.382</b>	≥ 0.200
B) Index of Negative and Positive Sera		<b>accepted</b>	According to specification
C) Sensitivity with working calibrators		<b>accepted</b>	According to specification
3. FINAL CONTROL date: 22/11/2022			
A) Blank	OD 450 nm	<b>0.043</b>	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	<b>0.014</b>	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	<b>0.464</b>	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	<b>1.166</b>	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.	<b>6</b>	
	OD 450 nm	<b>0.507</b>	
	CV%	<b>5%</b>	≤15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **22.11.2022**

Signed:   
 Released: Q.C.Manager